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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,034	07/24/2006	Laurence Christa	CHEP:015US	9442

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
09/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,034	CHRISTA ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The preliminary amendment of 12/16/05 has been entered in full. Claims 1-17 are canceled. New claims 18-48 are added.

The preliminary amendment of 12/17/07 has been entered in full. New claim 49 is added.

Claims 18-49 are under pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 18-26 and 37-43 drawn to compositions comprising a polypeptide, including compositions comprising a polypeptide and a cell, and drawn to a cell *per se*.

Group II, claim(s) 27-36, drawn to a method of treating a subject comprising administering a composition comprising a polypeptide.

Group III, claims 44-49, drawn to an *in vitro* method of stimulating cell growth, or inhibiting apoptosis, comprising contacting cultured cells with a polypeptide.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-III appears to be that they all relate to a polypeptide comprising a sequence having at least 90% identity with residues 36-175 of SEQ ID NO: 1.

However, the polypeptide of SEQ ID NO: 1 is taught by the prior art. SEQ ID NO: 1 is a human sequence of 175 amino acids. This polypeptide sequence is taught in

Figure 2 (pg 5091) of Lasserre et al (1992. Cancer Research. 52: 5089-5095; reference C2 on the 7/24/06 IDS). On pg 5092, Lasserre et al term this protein HIP based on the expression of the gene (hepatocellular carcinoma, small intestine, pancreas). The instant specification acknowledges that HIP and SEQ ID NO: 1 are the same by titling the specification "HIP/PAP Polypeptide Compositions..." and citing Lasserre et al (¶54 of the published application) when describing the expression of HIP/PAP gene. Thus, the prior art teaches a polypeptide comprising a sequence that is 100% identical to residues 36-175 of SEQ ID NO: 1. Furthermore, the prior art also teaches compositions comprising said polypeptide and a cell, as recited in claim 37. Specifically, Cervello et al (1999. Ann NY Acad Sci. 963: 53-58) teaches cell cultures of human hepatoma cell lines that express HIP/PAP. Such cultures are compositions comprising a polypeptide a sequence that is 100% identical to residues 36-175 of SEQ ID NO: 1, and a cell.

Therefore, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of species in Group I or III

If Group I or III is elected, an election of species is also required as follows:

These Groups contains claims directed to more than one species of cell of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(a) hepatocyte and (b) bone-marrow stem cell.

The claims are deemed to correspond to the species in the following manner:

1. Claims 38, 39, 42, 45, 46 and 49 correspond to species (a).

2. Claims 40 and 47 correspond to species (b).

The following claim(s) are generic: 1-26, 37, 41, 43, 44 and 48.

The species of cell listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each cell expresses a different selection of genes, resulting in expression of different proteins that render the cells structurally different. Lack of unity is shown because these cells lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicant is required, in reply to this action, to elect a single species of cell to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election of species in Group II

If Group II is elected, an election of species is also required as follows:

This Group contains claims directed to more than one species of subject of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Subject with (a) Hepatitis B, (b) Hepatitis C, (c) Urea Cycle defects, (d) Familial hypercholesterolemia, (e) Alcohol induced cirrhosis, (f) Glycogen Storage Disease, (g) Autoimmune Hepatitis, (h) Primary Hyperoxaluria type 1, (i) Cryptogenic cirrhosis, (j) Crigler-Najjar syndrome type 1, (k) Congenital Hepatic Fibrosis, (l) Neimann-Pick Disease, (m) Primary Biliary Cirrhosis, (n) Familial Amyloidosis, (o) Biliary Atresia, (p) Hepatocellular Carcinoma, (q) Primary Sclerosing Cholangitis, (r) Hepatoblastoma, (s) Alagille Syndrome, (t) Hemangioendothelioma, (u) Familial Cholestasis, (v) Non-Carcinoid neuroendocrine tumor, (w) Drug induced liver failure, (x) benign liver tumor, (y) other malignant liver tumor, (z) Budd-Chiari syndrome, (aa) Alpha-1-antitrypsin deficiency, (bb) Wilson Disease, (cc) Hemochromatosis, (dd) Tyrosinemia, (ee) Protoporphyria and (ff) Cystic fibrosis.

The claims are deemed to correspond to the species in the following manner:

1. Claims 30-34 each encompass one or more the species. Chronic liver failure, acute liver failure, liver necrosis, need for liver resection or transplant, liver cirrhosis can be caused by one or more of species (a)-(ff). Hepatic cancer as recited in claim 33 encompasses any malignant neoplasm including species (p), (r), (t), (v) and (y).

2. Claim 35 recites species (e) and (w) as part of Markush-type group that also includes cirrhosis of viral cause, which encompasses species (a) and (b).

3. Claim 36 recites each of species (a)-(ff) as part of a Markush-type group.

The following claim(s) are generic: 27-29.

The species of subject listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each subject has a different disease with a different etiology. The etiology results in different molecular structural differences in damage caused by the disease. Lack of unity is shown because these cells lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicant is required, in reply to this action, to elect a single species of subject to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647